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Multidimensional rehabilitation programmes for adult cancer survivors (Protocol)

Mills M, Black A, Campbell A, Cardwell CR, Galway K, Donnelly M

This is a reprint of a Cochrane protocol, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2009, Issue 2

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[Intervention Protocol]

Multidimensional rehabilitation programmes for adult cancer survivors

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effectiveness of multidimensional rehabilitation programs in terms of maintaining or improving the physical and psychosocial well-being of adult cancer survivors.

The review will evaluate the extent to which:

- Professionally led multidimensional rehabilitation programs achieve better outcomes than standard services for patients with cancer and their caregivers
- Rehabilitation programmes exert a different impact on different domains (e.g. psychological health, physical functioning)
- Different modes of delivery and different settings influence outcomes
- There is relationship between the number, duration and intensity of rehabilitation sessions and degree of change in measured outcomes.

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BACKGROUND

Advances in early detection of cancer, improved treatments and an ageing population have resulted in an increase in the number of people living with and surviving cancer. Cancer Research Statistics (CRUK 2008) indicate that the average five-year relative survival rate for all cancers in the UK has now reached 50%, with survival rates for some cancers being as high as 87% (malignant melanoma) and 96% (testicular cancer). As survival rates continue to improve annually, cancer is becoming recognised as a chronic or long term condition for many patients.

Research on cancer survivorship has started to flourish, though there is a lack of consensus about the exact definition of a 'survivor'. In the US the term encompasses the entire experience of living with, through and beyond a diagnosis of cancer and includes family members, friends and caregivers affected by the experience (NCI 2004). The definition in the UK from the Cancer Reform Strategy 2007 describes a survivor as someone who has completed initial treatment and has no apparent evidence of active disease, or is living with progressive disease but is not in the terminal phase of their illness, or someone who has had cancer in the past. This will be the definition adopted by the authors for the purposes of this review.

The increasing number of survivors presents a challenge for cancer services. People surviving or living with cancer tend to experience a variety of short and long-term physical and psychosocial adverse effects which may be directly related to their disease or to the side-effects of treatment (Aziz 2003). Physical issues include fatigue, reduced physical and cognitive capacity and changes in sexual activity (Schroevers 2006) and medical problems such as osteoporosis, thyroid, heart and lung conditions are common (Schultz 2003). In addition psychosocial problems include anxiety, depression, low self-esteem and fear of recurrence and death (Jefford 2008). Indeed international studies have shown rates of emotional distress in cancer patients ranging from 35 to 45% (Bultz 2008). The combined effect of physical and psychosocial problems may give rise to societal and interpersonal issues including lifestyle changes and the disruption of home and family roles (Aziz 2002). At the time of diagnosis and during primary treatment, support and reassurance may be more accessible from health care staff. However, following treatment completion many patients feel isolated or abandoned (Cardy 2006; Jefford 2008) and the importance of ongoing personalised information and support relating to past, present and possible future issues has been identified as an essential component of care for this patient group (Jefford 2008).

There is widespread recognition now of the importance of addressing the long-term needs of cancer survivors. In the US, a National Coalition for Cancer Survivorship (NCCS 2009) has been created and in conjunction with other leading medical groups NCCS is producing evidence-based guidelines and implementing cancer survivorship care plans (Hewitt 2006). Meanwhile, in the UK the Cancer Reform Strategy 2007 has highlighted that survivors of cancer should be provided with the assistance they need to resume as normal a life as is possible. A National Cancer Survivorship Initiative (Cancer Reform Strategy 2007) is being implemented; this will consider a range of approaches to survivorship care and ways in which these approaches may best be tailored to meet the needs of individual patients. Some of the suggested approaches include education, self-care, psychological and spiritual support, nutritional advice and the provision of rehabilitation programs.

Rehabilitation has previously been defined as 'a planned program in which the person progresses towards, or maintains the maximum degree of physical and psychological independence of which he is capable' (Roper 1987). Rehabilitation programs have been proven to be beneficial for other chronic diseases such as heart disease (Jolliffe 2001), multiple sclerosis (Khan 2008), and chronic obstructive pulmonary disease (Lacasse 2006). Owing to the success of these programmes, cancer specific rehabilitation programs have been developed in various countries, with initiatives in America, Australia and the Netherlands leading the way. Previous reviews have focused on single interventions such as exercise (Cramp 2008; Markes 2006) or psychological (Edwards 2004) interventions. While exercise has been proposed to have long-term beneficial outcomes for patients it appears that psychological interventions on their own have only a short-term impact. In addition research suggests that interventions providing information alone have been less effective. It has been proposed that multidimensional programs that provide people with the skills to manage their own care may lead to improvements in knowledge, coping behaviour, self-efficacy and enhanced quality of life (QoL) (Corner 2007).

Thus, the aim of this review is to assess the effectiveness and added value of multidimensional rehabilitation programs for cancer survivors, in order to facilitate the development of evidence-based cancer rehabilitation programmes.

This review will collate and systematically assess the best available research evidence on the effectiveness of multidimensional rehabilitation programmes for adult cancer survivors. If evidence is available to support multidimensional programmes, it will allow service providers to develop programmes for cancer survivors to facilitate targeted support required to rebuild their lives.

OBJECTIVES

To assess the effectiveness of multidimensional rehabilitation programs in terms of maintaining or improving the physical and psychosocial well-being of adult cancer survivors.

The review will evaluate the extent to which:

- Professionally led multidimensional rehabilitation programs achieve better outcomes than standard services for patients with cancer and their caregivers

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- Rehabilitation programmes exert a different impact on different domains (e.g. psychological health, physical functioning)

- Different modes of delivery and different settings influence outcomes

- There is relationship between the number, duration and intensity of rehabilitation sessions and degree of change in measured outcomes.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) (including quasi-RCTs) of multidimensional interventions for adult cancer survivors.

Types of participants

Adults aged 18 and over, who have been formally diagnosed with any type or stage of cancer and who have completed their primary active treatment regime e.g. surgery, chemotherapy or radiotherapy. Children will not be included in this review as the follow-up care they receive generally differs from that of adults. There will be no restrictions on gender, ethnicity or type of setting.

Types of interventions

Interventions must contain a physical component (e.g. exercise, dietary regime) and a psychosocial component (e.g. counselling, cognitive behaviour therapy, psychoeducational strategies), delivered in person, via telephone or web-based, in any setting (e.g. home, community-based or clinic visit), individual or group sessions and targeted at improving physical and psychosocial well being. Interventions should involve two or more interactive sessions and must be delivered by a health care professional. The review will exclude programs delivered by lay people and those which focus on 'return to work' as a primary outcome as this will be included within another Cochrane review.
Control groups may include those who have not received an intervention or who have received 'standard care'; or a lower level of intensity; or a different mode of administration; or different settings.

Types of outcome measures

Primary outcomes

Primary endpoints must include a physical outcome and a psychosocial outcome. Physical outcomes may include changes in physical or functional status (e.g. exercise tolerance, physical fitness, weight control, dietary intake) or symptom control (e.g. pain, fatigue). Psychosocial outcomes may include measures of QoL, self-efficacy, anxiety or depression. These measures must be assessed using established validated scales (e.g. EORTC, FACT, SF36, Beck Depression Inventory or Hospital Anxiety and Depression Scale).

Secondary outcomes

Patient adherence and satisfaction with the rehabilitation programmes.
Adverse outcomes: we will document all adverse outcomes reported in the trials.

Search methods for identification of studies

Electronic searches

To identify studies for inclusion in this review, detailed search strategies have been developed for each of the following electronic databases:

- Cochrane Central Register of Controlled Trials (CENTRAL) (up to latest issue)
- MEDLINE (start to present date)
- EMBASE (start to present date)
- CINAHL (start to present date)
- PsychINFO (start to present date)

The search uses a combination of controlled vocabulary and free text terms developed in consultation with an expert medical librarian and with Trial Search Co-ordinators for the Cochrane Gynaecological Cancer Review Group. In addition we will use the Cochrane Handbook 2008 search strategy for optimal sensitivity in identifying randomised controlled trials. The search strategy has been developed for MEDLINE and will be revised appropriately for each database. The MEDLINE search terms are presented in two sections to reflect each element of the review title(Appendix 1).

Language

No language restriction will be placed on the searches. Translation services are available within Queen's University, Belfast. Initially foreign language abstracts will be translated for the application of inclusion and exclusion criteria, and where necessary the methods,

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results and discussion sections will be translated for inclusion in the review.

Searching other resources

Reference lists from all identified studies and from relevant published reviews on similar topics will be checked for additional appropriate studies.
First authors of significant papers will be contacted to find other potentially relevant studies.

Data collection and analysis

Selection of studies

The results of the searches will be downloaded into a reference manager database (RefWorks) and duplicates will be removed. The remaining titles and abstracts will be reviewed by two review authors and independently screened for suitability, according to the following basic criteria:

- RCT (including quasi-RCT)
- Intervention including physical and psychosocial component
- Intervention carried out on two or more occasions
- Adult (aged 18 and over) cancer patients
- Patients not receiving primary active treatment (e.g. surgery, chemotherapy or radiotherapy)
- Outcomes to include a physical outcome measure and psychosocial outcome measure

Studies which do not clearly meet the inclusion criteria will be excluded. Where necessary, the full-text of articles will be obtained to determine if trials meet the criteria. Any discrepancy in the exclusion of trials will be resolved by discussion between the two review authors. If an agreement cannot be reached regarding the inclusion of an article then a third review author will be consulted in order to reach a decision. A list of excluded trials and reasons for exclusion will be recorded.

Data extraction and management

Two review authors will independently extract data from the original reports using pre-designed data extraction forms. Data extracted will include the following information:

- General: author, year of publication, title, journal, country and language of publication
- Trial: study design, randomisation, allocation concealment, level of blinding
- Participant: diagnosis, cancer stage, age, gender, ethnicity, sample size and distribution of participants in each arm of the trial
- Intervention and control: components of intervention, method of delivery, setting, health professional involved, length of intervention, frequency, control intervention characteristics
- Methodological quality: See below
- Outcomes: Physical, psychosocial, adherence, satisfaction and adverse events

Assessment of risk of bias in included studies

Two review authors will independently assess the methodological quality of the selected studies and using a quality appraisal checklist code them as follows:

- Random allocation

a) Adequate e.g. computer-generated random sequence, or table of random numbers
b) Quasi-randomised e.g. date of birth, day of week
c) Unclear e.g. not reported

- Allocation concealment:

a) Adequate e.g. allocation concealment could not be foretold
b) Inadequate e.g. research or health care staff aware of which arm participants would be assigned
c) Unclear e.g. not reported

- Blinding:

With this type of intervention participants or staff cannot be blinded to the intervention. However, the outcome assessors can be blinded and this will be coded as:
a) Yes
b) No
c) Unclear

- Incomplete data:

a) Yes: Attrition rate / lost to follow-up clearly accounted for
b) No
c) Unclear
The information collected will be used in the Risk of Bias tool available in RevMan 5 to assess the quality of each study.

Sensitivity analysis

If sufficient trials of adequate quality, in comparable populations with similar interventions using comparable outcomes are identified, then meta-analysis of primary and secondary end-points will be carried out. Data will be entered into RevMan 5. For dichotomous outcome variables we will calculate relative risks (RR) and standard errors (SE) comparing the treatment to the control group for each included study. Where appropriate, we will calculate a pooled RR and 95% confidence interval (CI) using a fixed or random effects model depending upon study heterogeneity. For continuous outcome variables, we will calculate the difference in mean (and SE) between the treatment and control group for each included study. Where appropriate, we will calculate a pooled difference in mean and 95% CI using a fixed or random effects model

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depending upon study heterogeneity. If individual studies have used different scales to measure the continuous outcome variables standardised mean difference (SMD) will be used instead. Where high-risk studies have been identified by the Risk of Bias tool a sensitivity analysis will be carried out including only studies with suspected low risk of bias. We will assess heterogeneity using the I squared (I^2) statistic. If I^2 is greater than 25% this is indicative of heterogeneity and a random effects model will be used. If marked heterogeneity is suspected (greater than 75%), estimates will not be combined.

Where data is available, sub-group analysis will be conducted on: diagnostic group, age, gender, ethnicity, cancer stage (potentially curative, palliative), health care professional involved, setting (home, hospital, community), method of delivery (individual, group, in person, telephone or web-based), duration (short-term i.e. less than three months or long-term i.e. more than three months) and frequency of intervention (i.e. weekly or monthly). Funnel plots will be used to investigate evidence of publication bias or other differences in effect between smaller and larger studies. If we cannot find sufficient high quality RCTs to pool the data, we will provide a description of the studies identified and their main findings.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE Search Strategy

- Cancer

1 Cancer.mp. or Neoplasm/ 2 Neoplasm$.mp. 3 Carcinoma/ or carcinoma.mp. 4 Malignan$ 5 neoplasms/rh[rehabilitation] 6 tumo?r$

- Rehabilitation Programs

1 Rehabilitation/ or Rehab$ program$.mp. 2 Self care support program$.mp. or Self Care/ 3 Self management program$.mp. 4 self management training.mp. 5 Self-help group$.mp. or self-help groups/ 6 Self help group$.mp. 7 selfhelp group$.mp. 8 Social support/ or Social support intervention$.mp. 9 Support group$.mp. 10 group support.mp. 11 group therapy.mp. or psychotherapy, Group/ 12 group coping.mp. 13 Counsel?ing.mp. or exp counselling/ 14 Psychotherapy.mp. or exp Psychotherapy/ 15 psychosocial therapy.mp. 16 psychological intervention$.mp. 17 psychosocial intervention$.mp. 18 psychological support.mp. 19 psychosocial support.mp. 20 Relaxation techniques/ or relaxation training.mp. 21 patient education.mp. or patient education as Topic/ 22 educational interventio$.mp. 23 educational therapy.mp. 24 Cognitive therapy.mp. or Cognitive Therapy/ 25 cognitive psychotherapy.mp. 26 cognitive behavio?r therapy.mp. 27 behavio?r therapy.mp. or behavior therapy/ 28 Social work.mp. or Social Work/ 29 dietary services.mp. or Dietary services/ 30 Nutritional Sciences/ 31 dietary regime or nutrition or diet NEAR composition or dietary supplement$ 32 healthy eating 33 physical exercise.mp. or Exercise/ 34 physical modalities.mp. or Physical Therapy Modalities/ 35 physiotherapy/ or physiotherapy.mp. 36 respiratory therapy/ or respiratory therapy.mp. 37 urinary incontinence/ or incontinence training.mp. 38 acupuncture/ or acupuncture.mp. 39 massage/ or massage.mp. 40 speech and language therapy.mp. 41 occupational therapy/ or occupational therapy.mp.

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HISTORY

Protocol first published: Issue 2, 2009

Date	Event	Description
2 February 2009	Feedback has been incorporated	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

MM is the main author and will be involved in all aspects of the protocol, including conception of the review, development of search strategies and drafting of the protocol. MD will provide editorial supervision of the protocol. All authors (MM, MB, AC, CC, KG, MD) will be involved in the development of the review and in pairs they will identify eligible studies, conduct quality assessments of eligible studies and extract data from the original studies. CC will provide statistical advice on meta-analysis.

DECLARATIONS OF INTEREST

None

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